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Application Serial No. 09/807,704  
Reply to Office Action of January 3, 2006

PATENT  
Docket: CU-2513

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE  
(Case: CU-2513)

PATENT

In re Application of: Stig Jansson  
et al.

Serial No.: 09/807,704

Filed: July 25, 2001

For: Process for Separating Lipids  
and Proteins from Biological  
Material

Before Examiner: Winston O.  
Randall

Group Art Unit: 1655

Commissioner for Patents  
P. O. Box 1450  
Alexandria, VA 22313-1450

DECLARATION UNDER 1.132

Sir:

The attached Declaration is provided as evidence to traverse the rejections of the claims.

Respectfully submitted,  
LADAS & PARRY

Dated: June 30, 2006

By:   
Attorney for Applicant  
Patricia Hoyle, Reg. No. 54187  
(312) 408-2535

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### DECLARATION

The undersigned, Stig Jansson, holding a degree in Master of Science in Fisheries, specialized in processing, being employed as a research scientist in the field of fish processing at SINTEF (The Foundation for Scientific and Industrial Research at the Norwegian Institute of Technology) since year 2000, and being the inventor of the invention described in Norwegian patent application no. 1993 3009 hereby testifies to the following:

In the year 1993 I was one of the two entrepreneurs who initiated the company Marine Lipids and later employed in the company in 1994 as a scientist responsible for the R&D and quality assurance of fish oil products. Marine Lipids had a long-standing experience with the development of fish oil products through the owners, the major cod liver oil producers in Norway, which in 1993 had approximately 30 % of the world production of the specific product Cod Liver Oil. These (four) companies had a solid history in the field of processing and business of cod, cod liver and oils, and goes back as far as year 1936 at my knowledge. This means that approximately 70 years experience in the specific field was accumulated in-house in Marine Lipids.

Since the year of 1853 the chosen method of extraction, based on quality point of view, has been direct steam heating and later on indirect steam heating of cod liver to liberate oil thereof. Marine Lipids products has also been produced (cod liver oil and fish oil) by the previously known method of isolating the oil through high temperature boiling/steam extraction of the oil.

The company changed some of its oil production to the low-temperature process disclosed in Norwegian patent application 1993 3009 in the year 1994, but never optimized the process being content with producing oil of a superior quality at refrigeration temperatures of 4-6°C.

Also other companies started extracting superior quality oil by the low temperature method of Norwegian patent application 1993 3009 after the patent rights to the low temperature extraction method had been lost by Marine Lipids through unforeseen circumstances. However, none of these companies optimized the process either by attempting to perform the process through finding the optimal extraction temperature for the oil. The situation at the filing date of the priority application for the present patent application (October 21, 1998) was thus that oil was either extracted at water vapour temperatures (around 80-100°C) or at refrigeration temperatures (around 4-6°).

The general knowledge around extraction processes for animal or vegetable oil at the filing date of the present patent application was that in order to obtain superior quality oil, i.e. with its natural content of trace materials, enzymes, co-factors and other biologically important ingredients intact in their natural condition, the extraction temperature should remain at or below the natural habitation temperature of the fish, i.e. not exceeding 10-15°C. Thus there was no incentive for the person skilled in the art to look for any other temperature at which the extraction might be performed, and also on account of the uncertainty around extracting the oil at temperatures above the natural habitation temperatures of the fish, and also on account of the success of the low-temperature extraction (around 4-6°C), extraction temperatures above 15°C were even counter-indicated, also pointing away from searching for temperatures above the habitation temperatures of the fish.

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In 1998 no other company had even tried to optimize the low-temperature extraction process either because the known process was providing fish oil of adequate quality, not giving any incentive to look for other possible ways to perform the extraction, or because the person skilled in the art was reluctant to elevate the extraction temperature in fear of losing the improved oil quality which was proven to be present in the already known product. Consequently, in 1998 there existed a prejudice in the art against performing an oil extraction process at temperatures above 4-6°C if a superior quality oil was to be obtained.

In 1998 it was thus surprising to find that it was possible to elevate the temperature in the extraction process without losing or reducing the quality of the oil or denaturing or otherwise deteriorating the naturally occurring ingredients of the oil. The improvement in elevating the extraction temperature was, however, evident after the conception of the inventive idea, since the elevated temperatures would provide an opportunity to perform the extraction at larger speeds than the previously known low-temperature process, and additionally without having to invest in expensive new process equipment or extra machinery. The larger speed in production results in a low exposure of oxidative stress as function of *Time X Temperature*. However, what was to be determined at the conception of the inventive idea, was to verify that elevating the temperature to the limits defined in the patent application would not have any quality-reducing effect on the end products from the extraction. To my knowledge, I was the first person to verify that it was possible to perform the oil extraction process at temperatures below the denaturing temperatures of the proteins in the fish oil, and that was also the core of my invention.

Signed this day of June 23, 2006  
Location: Trondheim, Norway



Stig Jansson